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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

RETROPHIN, INC., a Delaware Corporation Plaintiff, v. QUESTCOR PHARMACEUTICALS, INC., a California Corporation, Defendant.	Case No. 8:14-CV-00026 – JLS (JPR) The Hon. Josephine L. Staton **DEFENDANT'S REPLY MEMORANDUM IN SUPPORT OF MOTION TO DISMISS PLAINTIFF'S COMPLAINT WITH PREJUDICE** Hearing Date: May 30, 2014 Time: 2:30 p.m. Court Room: 10A

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INTRODUCTION

Questcor Pharmaceuticals, Inc.'s ("Questcor") Motion to Dismiss identified three realities that doom Retrophin, Inc.'s ("Retrophin") Complaint. ***First***, Novartis AG ("Novartis") never sought to market Synacthen in the United States during its 40 years of ownership, despite supposed H.P. Acthar Gel ("Acthar") monopoly profits that would have attracted such entry. Thus, Synacthen's seller was not a potential competitor. ***Second***, Retrophin does not allege likely FDA approval of Synacthen for Acthar's indications, an omission wholly understandable in light of better-resourced Novartis' failure ever to try. Thus, the Synacthen assets Retrophin sought could not support non-speculative entry against Acthar. ***Third***, in sharp contrast, Retrophin expects swiftly to compete with Acthar through its own RE-034, one of many synthetic ACTH therapeutics that Retrophin admits numerous firms are developing.

These realities, as Questcor showed in its Memorandum in Support of its Motion to Dismiss ("MTD"), preclude Retrophin from alleging that Questcor's licensing of Synacthen violates the antitrust laws. Retrophin fails to allege actual or threatened injury, and thus lacks standing, because any harm to Retrophin rests upon a chasm of contingencies that Retrophin's Complaint fails to bridge, including (i) lack of any allegations that Retrophin likely would obtain Synacthen's FDA approval for Acthar's indications; and (ii) Retrophin's admissions that it expects to enter more swiftly and surely through RE-034. Retrophin lacks antitrust injury under indistinguishable Ninth Circuit authority and because any asserted harm flows from an inability to engage in conduct that, under its own (incorrect) theory, would not improve competition. Retrophin identifies no valid theory of competitive harm because it does not (and could not) allege that seller Novartis stood ready to enter the relevant markets. Retrophin's Opposition to Questcor's Motion to Dismiss ("Op.") offers no rejoinder to these straightforward reasons why the Court should dismiss the Complaint, or the three elemental facts underlying them.

1. ***No antitrust standing.*** Questcor demonstrated that Retrophin lacks antitrust standing because Retrophin fails to allege actual or threatened injury-in-fact; indeed, any harm to Retrophin is wholly speculative. Retrophin fails to allege non-speculative injury from Questcor's conduct because Retrophin nowhere alleges likely FDA approval of Synacthen for

Acthar's indications, yet admits that it expects swift entry through Synacthen-equivalent RE-034. Retrophin's primary response – that it need not allege probable FDA approval of Synacthen – is refuted by Retrophin's own argument that only a "***likely*** entrant" can begin to allege the type of antitrust claim it brings (Op. 2 (quoting 3 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law, ¶ 701d, at 197-99 (3d ed. 2007) (emphasis added) (internal quotations omitted))). Retrophin's contention that it could amend to allege likely FDA approval is fatally contradicted by its admission that Novartis, with its vast resources and assertedly great incentive to enter, never sought such approval (Compl. ¶¶ 4, 46). Retrophin's investor statements that it expects rapid entry with RE-034 – which the Opposition does not deny – put the lie to Retrophin's conclusory allegation that Synacthen offered a surer and swifter entry path. In light of Retrophin's admissions, any harm to Retrophin from Questcor's licensing of Synacthen is wholly speculative.

2. ***No antitrust injury.*** Retrophin lacks antitrust injury under *Lucas Automotive Engineering, Inc. v. Bridgestone/Firestone, Inc.*, 140 F.3d 1228 (9th Cir. 1998), which holds that a disappointed bidder, like Retrophin, lacks antitrust injury as a competitor to challenge a rival's acquisition of assets with which the plaintiff would prefer to use to compete. Retrophin cannot distinguish *Lucas*. By contrast, *Glen Holly Entertainment, Inc. v. Tektronix, Inc.*, 352 F.3d 367 (9th Cir. 2003), on which Retrophin relies, is inapposite because the court held antitrust injury to exist based on the plaintiff's status as a ***customer***, a circumstance absent here. Questcor also demonstrated that Retrophin lacks antitrust injury because, on Retrophin's (baseless) theory that Synacthen could enable meaningful competition against Acthar, the course of conduct Retrophin proposed – to control ***both*** Synacthen ***and*** RE-034 – would not improve competition. Retrophin's response, that RE-034's entry is itself speculative, founders on Retrophin's statements to its investors that it expects to enter through RE-034 swiftly.

3. ***No harm to competition.*** The same realities that leave Retrophin's injury speculative similarly render speculative any competitive harm from the conduct Retrophin challenges. Retrophin also alleges no valid theory of harm to competition for the separate – but decisive – reason that Retrophin's Complaint does not fall within the extremely narrow circumstances in

which courts permit challenges to acquisitions that purportedly diminish potential competition. Because Novartis was not a likely entrant when it held Synacthen, Retrophin cannot challenge any diminution of potential competition from Questcor's licensing of Synacthen. Retrophin's request that this Court forge new law, and permit a prospective entrant to mount an antitrust claim whenever it contends the incumbent acquired assets with which the prospective entrant would prefer to compete (even if those assets never supported competitive entry), lacks foundation. No court has ever sustained such an antitrust theory. Retrophin's Complaint presents no occasion for breaking such new ground because Retrophin (i) alleges no reason why Retrophin is better situated to compete against Acthar with Synacthen than Novartis; and (ii) admits another, swifter entry path through RE-034.

4. ***No market power.*** Retrophin's Opposition also fails to rescue its deficient market power allegations. Retrophin's allegation that Acthar's per vial price increased from $50 to $28,000 fails to directly allege market power because Retrophin avers no decrease in output. Retrophin's public admissions that numerous firms are pursuing "open source" synthetic ACTHs refute Retrophin's contention that developing a new drug, as Retrophin did with RE-034, poses a significant entry barrier. Finally, Retrophin's contention that FDA approval is a sky-high entry barrier that protects an "air tight monopoly" (Op. 19) fatally conflicts with Retrophin's contention that its failure to enter through Synacthen gives rise to concrete cognizable harm.

The Court accordingly should bring this meritless case to an end by granting Questcor's Motion to Dismiss with prejudice. Having elected to stand on its Complaint rather than amend as of right after receiving Questcor's motion, Retrophin should not be permitted another opportunity. Moreover, Retrophin's inability to alter the three central realities identified above that doom its Complaint renders any amendment futile.

I. RETROPHIN FAILS TO ALLEGE ANTITRUST STANDING OR ANTITRUST INJURY

Retrophin does not contest that courts must rigorously enforce the essential elements of antitrust standing and injury in suits brought by putative rivals. Retrophin's Opposition fails to meet Questcor's showing that, when subjected to such "careful[] scrutin[y]," *Alberta Gas*

Chems. Ltd. v. E.I. du Pont de Nemours & Co., 826 F.2d 1235, 1239 (3d Cir. 1987), Retrophin sufficiently alleges neither.

A. The Complaint Fails To Allege Antitrust Standing

Antitrust standing requires, *inter alia*, both (i) actual or threatened injury-in-fact; and (ii) non-speculative harm. *See, e.g.*, *Somers v. Apple, Inc.*, 729 F.3d 953, 963 (9th Cir. 2013) ("the fact of injury . . . must be alleged at the pleading stage"); *Catlin v. Wash. Energy Co.*, 791 F.2d 1343, 1347 (9th Cir. 1986) (mere "speculation" insufficient); *Sprint Nextel Corp. v. AT&T Inc.*, 821 F. Supp. 2d 308, 316-17 (D.D.C. 2011) (antitrust laws do not "authorize suits by those whose allegations of threatened injury amount to little more than conjecture"). Questcor demonstrated that Retrophin fails to allege non-speculative injury (MTD 4-5, 11-13). In particular, Questcor demonstrated that Retrophin's injury hinges, among other things, on (i) FDA approval that Retrophin does not – and cannot – allege is likely; and (ii) Retrophin's inability to compete against Acthar through another path, which Retrophin's admission that it expects swift entry through RE-034 refutes. Retrophin offers no persuasive rejoinder.

1. *Retrophin fails to allege injury-in-fact because it does not and cannot allege likely FDA approval of Synacthen for Acthar's indications.* Under *Andrx Pharms., Inc. v. Biovail Corp. Int'l*, 256 F.3d 799 (D.C. Cir. 2001), Retrophin fails to allege injury-in-fact because its Complaint nowhere avers that approval of Synacthen for Acthar's indications is "probable." *Id.* at 808. Retrophin's response – that a potential competitor need only allege "intent and preparedness" to enter (Op. 12) – misses the point. As *Andrx* held, a potential competitor seeking to enter through an FDA-approved drug cannot allege "preparedness" ***unless*** FDA approval is "probable." 256 F.3d at 808. Retrophin's further argument that this Court should ignore *Andrx* (Op. 13) founders on Retrophin's own Areeda-backed argument that only an acquisition of a "***likely***" entrant can cause cognizable harm (Op. 2) (internal quotations omitted). As *Andrx* reasoned, no harm is likely unless FDA approval is probable.

As Retrophin's embrace of the Areeda "likely entrant" standard reflects, the *Andrx* test makes good sense. After all, as *Andrx* observed, the "intent and preparedness" test implements the requirement imposed by both Article III and the Clayton Act of a concrete actual or

threatened injury, 256 F.3d at 806-07; and without probable FDA approval, harm is not "likely" (Op. 2). By contrast, Retrophin's argument – that "preparedness" requires ***no*** allegation whatsoever as to the likelihood of actual successful entry (Op. 12-13) – would impermissibly confer standing on parties with little more than a hope to compete. Retrophin's own cases explain that a desire to compete without sufficient "indicia of ultimate success" cannot support standing. *In re Dual-Deck Video Cassette Recorder Antitrust Litig.*, 11 F.3d 1460, 1466 (9th Cir. 1993). Not surprisingly, the ANDA cases Retrophin cites are distinguishable.[1] Put simply, when, as here, the plaintiff's injury-in-fact ***depends*** on FDA approval, no actual or threatened injury exists unless such approval is likely.[2]

Implicitly acknowledging that it must allege probable FDA approval of Synacthen for Acthar's indications, Retrophin asks this Court to excuse its pleading failure because "it is easy to infer that allegation from the facts in the Complaint" (Op. 14). As an initial matter, "it is axiomatic that the complaint may not be amended by the briefs in opposition to a motion to dismiss." *Car Carriers, Inc. v. Ford Motor Co.*, 745 F.2d 1101, 1107 (7th Cir. 1984). Moreover, no facts Retrophin actually alleges support any such inference. On the contrary, Retrophin's allegation that data Novartis possesses from Synacthen's use outside the United States could enable immediate Phase III trials – the only fact to which Retrophin points (Op. 12-13) – cuts decisively the other way. According to Retrophin, Acthar's "extortionate prices" and

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[1] The plaintiff in *Roxane Labs., Inc. v. SmithKline Beecham Corp.*, No. 09-CV-1638, 2010 WL 331704 (E.D. Pa. Jan. 26, 2010), alleged that "it believed that the FDA was likely to approve" its FDA application in a specific month. *Id.* at *3-4. The court accordingly did not need to decide whether to follow *Andrx*. *See id.* The plaintiff in *Shionogi Pharma, Inc. v. Mylan, Inc.*, No. 10-1077, 2011 WL 3860680, at *5 (D. Del. Aug. 31, 2011), had already *filed* a drug application with the FDA. As for *Xechem, Inc. v. Bristol-Myers Squibb Co.*, 372 F.3d 899 (7th Cir. 2004), the court gave no indication as to whether the plaintiffs alleged likely FDA approval and made no effort to assess "preparedness." *Id.* at 902. In any event, as Retrophin concedes (Compl. ¶¶ 32, 58), obtaining approval for a new drug is far harder than the approval pathway for a generic drug (MTD 13-14 n. 28).

[2] Retrophin's argument that it can establish preparedness through RE-034 (Op. 13) is misplaced. The injury Retrophin asserts is its inability to market ***Synacthen***. The relevant "preparedness" for standing, therefore, is preparedness to enter ***through Synacthen***. Retrophin's further contention – that it could help patients immediately in Phase III without final approval (Op. 4 n.2) – is at war with FDA regulations (MTD 14 n.29).

purported monopoly profits should have attracted entry (Op. 17). Yet Novartis, with its massive resources and data that supposedly could facilitate entry, made no attempt to obtain FDA approval for the 40 years it held Synacthen (Compl. ¶¶ 4, 46). Neither the Complaint, nor Retrophin's Opposition, gives any basis to infer that Retrophin would succeed in obtaining an approval that Novartis, with at least the same ability and incentive to enter, never attempted. Put simply, Retrophin has "plead[ed] itself out of court." *U.S. Gypsum Co. v. Ind. Gas Co.*, 350 F.3d 623, 626 (7th Cir. 2003).

For these reasons, Retrophin not only does not, but could not allege in good faith that FDA approval for Synacthen's indications is likely. This is why *Andrx*'s disposition lends Retrophin no assistance. The *Andrx* court reversed a dismissal with prejudice because the facts before it (including, notably, that the FDA ***already*** approved the plaintiff's product) demonstrated that the plaintiff there "could have alleged its intent and preparedness to enter the market by claiming that FDA approval was probable." 256 F.3d at 808. Here, in sharp contrast, the facts Retrophin alleges make plain that it cannot supply the allegations *Andrx* requires.

Even if Retrophin had met the "intent and preparedness" test, lack of probable FDA approval renders any harm to Retrophin too speculative to support standing.[3] Retrophin's retort – that some of Questcor's cases holding harm too speculative to support standing involve the conduct of third-parties (Op. 10 n.7; 13 n.11) – is precisely the point. Without the approval of a third party (here, the FDA), any harm to Retrophin is too speculative to support standing. *See City of Pittsburgh v. W. Penn Power Co.*, 147 F.3d 256, 268 (3d Cir. 1998) (no standing where "no facts averred in the complaint" permitted the court to "speculate as to the likelihood" of approval); *see also Broadcom Corp. v. Qualcomm Inc.*, 501 F.3d 297, 320-22 (3d Cir. 2007) (no

[3] Speculative harm bars Retrophin from establishing standing under both Article III, *see Clapper v. Amnesty Int'l USA*, 133 S. Ct. 1138, 1150 (2013) (no Article III standing when plaintiffs' harm involved a "speculative chain of possibilities"), and Clayton Act Section 4, *see Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519, 543 (1983) ("*AGC*") (standing factors importantly include "the speculative measure of harm"). *Bubar v. Ampco Foods, Inc.*, 752 F.2d 445, 452-53 (9th Cir. 1985), makes clear that "preparedness" presents a distinct standing requirement from non-speculative harm.

antitrust standing to challenge defendant's acquisition where injury "highly speculative" because it depended on approval from standard setting organization).

2. *Retrophin's admission of swifter and surer entry through RE-034 additionally renders any harm speculative*. Questcor demonstrated that any harm to Retrophin is speculative for the additional reason that Retrophin admits expected swift entry into Acthar's markets through RE-034 (MTD 14-16). Retrophin's legal response, that efforts to "mitigate" its damages cannot render harm speculative (Op. 2), lacks foundation. As *CareFusion Corp. v. Medtronic, Inc.*, No. 10-CV-01111-LHK, 2010 WL 4509821 (N.D. Cal. Nov. 1, 2010), demonstrates, a plaintiff's response to challenged conduct (there, a decision to delay entry) can render harm speculative. *See id.* at *9. Here, Retrophin's admission of a superior entry vehicle in RE-034 (MTD 17-18) illustrates the absence of harm from the conduct it challenges. *See also Levine v. Cent. Fla. Med. Affiliates, Inc.*, 72 F.3d 1538, 1551 (11th Cir. 1994) (physician denied hospital privileges suffered no cognizable injury when admitted patients elsewhere); *Roland Machinery Co. v. Dresser Indus, Inc.*, 749 F.2d 380, 394 (7th Cir. 1984) (Posner, J.) (no antitrust claim when rival "cannot be kept out" of the relevant market).

Retrophin ultimately retreats to its contention that Questcor's conduct "delayed, and increased the cost, of, Retrophin's entry" (Op. 15). But Retrophin's admissions contradict the single thread-bare allegation (Compl. ¶ 59) that seeks to hold this story together. Retrophin cannot plausibly allege harm from failure to acquire Synacthen when Retrophin tells its investors that it has embarked on a "very fast-to-approval strategy" which "will allow early access" to RE-034 (MTD 15 (internal quotations omitted)). Put otherwise, Retrophin's admissions that it soon expects to enter through RE-034, which it admits is therapeutically equivalent to Synacthen (Compl. ¶ 57), permit this Court to ignore its boilerplate allegations of harm from Retrophin's failure to win Synacthen (MTD 6 n.13 (citing cases)).

Retrophin's further argument, that its admissions are somehow less meaningful because Questcor has not publicly stated its intent to pursue Acthar's indications for Synacthen (Op. 5-6, 11 n.9), is a red herring. For one thing, Retrophin has stated it expects RE-034 to swiftly obtain approval, allegations it could not make for Synacthen (MTD 15). That alone renders Retrophin's

harm speculative. Retrophin's ***additional*** public statements that it expects RE-034 to obtain approval before any other synthetic ACTH, including Synacthen (for whatever indications), only confirm the point (MTD 15). For another, Retrophin misreads Questcor's motion. Questcor did not "put Synacthen on the shelf" (Op. 5). On the contrary, Questcor plans to develop Synacthen for many therapeutic uses (MTD 4, 23 (citing filings)). The securities filing Retrophin cites – which puts the lie to the contention that Questcor could have achieved all its pro-competitive aims of acquiring Synacthen through Acthar (Op. 24) – does not rule out development of Synacthen for Acthar's current indications, including for IS and NS (Popofsky Decl. Ex. F, at 128). If Questcor ends up pursuing non-Acthar indications for Synacthen first, that would only confirm the only plausible inference from Retrophin's allegation that Novartis never sought Synacthen's FDA approval for Acthar's indications (Compl. ¶ 4): such approval is unlikely.

Finally, Retrophin cites inapposite cases for the proposition that "once an antitrust victim has demonstrated the fact of injury, the amount of damages" is tested under a more lenient standard (Op. 15, citing, *inter alia*, *Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 264 (1946); and *Story Parchment Co. v. Paterson Parchment Paper Co.*, 282 U.S. 555, 563 (1931)). But as courts have warned, "[t]he fact of injury . . . should not be confused with the extent of injury." *In re Visa Check/Mastermoney Antitrust Litig.*, 192 F.R.D. 68, 82-83 (E.D.N.Y. 2000), *aff'd*, 280 F.3d 124 (2d Cir. 2001). When, as here, harm to Plaintiff is speculative, the fact of injury is not sufficiently alleged and dismissal for lack of antitrust standing is appropriate. *See Gatt Commc'ns, Inc. v. PMC Assocs., LLC*, 711 F.3d 68, 79 (2d Cir. 2013) (dismissing complaint for lack of antitrust standing where plaintiff's injury was "highly speculative"); *Dominguez v. UAL Corp.*, 666 F.3d 1359, 1364 (D.C. Cir. 2012) (no antitrust standing where plaintiff "piles speculation atop speculation"); *Am. Med. Ass'n v. United Healthcare Corp.*, No. 00 Civ. 2800 (LMM), 2007 WL 683974, at *6 (S.D.N.Y. Mar. 5, 2007) (same).[4]

[4] One of Retrophin's cases, *Bubar v. Ampco Foods, Inc.*, 752 F.2d 445 (9th Cir. 1985), decisively supports dismissal here. The *Bubar* plaintiffs, like Retrophin, negotiated to acquire assets ultimately sold to another firm. *Id.* The court held plaintiffs' failure to obtain a "binding contract to acquire the assets" and status as "only a potential competitor" where "the speculative nature of the harm is increased" precluded standing. *Id.* at 452-53. So too here: that Retrophin (i) never had a contract with Novartis, (ii) fails to allege Synacthen's likely FDA approval, and

B. The Complaint Fails To Allege Antitrust Injury

Retrophin acknowledges that an antitrust injury must both be "the type the antitrust laws were intended to prevent" and "flow[] from that which makes [the conduct] unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977). Retrophin's Opposition fails to meet Questcor's showing that, for two reasons, Retrophin lacks antitrust injury.

First, Retrophin cannot distinguish *Lucas Automotive Engineering, Inc. v. Bridgestone/Firestone, Inc.*, 140 F.3d 1228, 1233 (9th Cir. 1998), which bars Retrophin from establishing antitrust injury. *Lucas* holds that, in a competitive bidding situation, a disappointed rival that sought to compete against the winner with the lost assets lacks antitrust injury to sue as a competitor as a matter of law. Retrophin's attempt to distinguish *Lucas* on the ground that the plaintiff in that case "failed to submit a conforming bid" (Op. 9) misreads the decision. The *Lucas* seller did not disqualify plaintiff's "final proposal," but rather fully weighed it against the winning bid. *Lucas*, 140 F.3d at 1230-31. Decisively, Retrophin makes no attempt to counter – because it cannot counter – the reasons (MTD 10) why *Lucas* presented an even stronger case for standing than Retrophin musters here. *Lucas* held that a ***completely*** excluded ***current*** rival lacked antitrust injury as a competitor to challenge a rival's acquisition of an exclusive license that the plaintiff coveted. *A fortiori*, a mere ***potential*** competitor such as Retrophin, which admits ***another*** entry path (RE-034), lacks antitrust injury.

Retrophin is equally wrong that *Glen Holly Entertainment, Inc. v. Tektronix, Inc.*, 352 F.3d 367 (9th Cir. 2003), limits *Lucas* (Op. 9-10). *Glen Holly* is inapposite because, as the court repeatedly stressed, the plaintiff there properly claimed injury as a "customer." *Id.* at 374, 376. Indeed, the court specifically reasoned that the plaintiff established "antitrust injury to its

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(iii) touts its likely swifter entry through RE-034 all undermine Retrophin's standing. *See* 2A Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law, ¶ 339b, at 109 (3d ed. 2007) ("If what makes causation doubtful is the number or improbability of steps in the chain from alleged violation to injury, then dismissal for remoteness is in order."). Retrophin's other cases are distinguishable. *McCaw Pers. Commc'ns, Inc. v. Pac. Telesis Grp.*, 645 F. Supp. 1166, 1168-1170 (N.D. Cal. 1986) (plaintiff and defendant pursued different assets and plaintiff had already "entered into a binding, written contract" to acquire the assets it sought); *Solinger v. A & M Records, Inc.*, 586 F.2d 1304, 1310-12 (9th Cir. 1978) (pre-*AGC*); *Chelson v. Oregonian Pub. Co.*, 715 F.2d 1368, 1370-71 (9th Cir. 1983) (same).

business" because "customers are the intended beneficiaries of the antitrust laws." *Id.* at 378.[5] *Glen Holly* accordingly in no way limits *Lucas* when, as here, a disappointed bidder-rival seeks standing as a competitor. Moreover, as the *Glen Holly* court observed, the case before it was "not *Lucas*" because the strategic alliance was "not strictly a merger case." *Id.* at 377. Here, by contrast, Retrophin (as in *Lucas*) asserts that merger principles (Clayton Act Section 7) apply to the conduct at issue here (Compl. ¶ 13). Finally, the logic of *Lucas* did not fit *Glen Holly*. Had the *Glen Holly* defendants not entered into the alliance, the plaintiff-customer would not have suffered any injury. By contrast, here as in *Lucas*, Retrophin would have suffered the same injury regardless of the identity of the party that acquired Synacthen.

Retrophin contends that Questcor's position proves too much because applying *Lucas* here would run counter to cases holding that foreclosed competitors can suffer antitrust injury (Op. 8-9). Retrophin's quarrel with the Ninth Circuit founders on the reality that Retrophin alleges no such foreclosure. Retrophin merely is one of many admitted potential entrants that lost a bid to acquire an asset that never had been used to facilitate competition in the relevant markets. This is far cry from the cases Retrophin cites from other circuits (Op. 8) such as *Gulf States Reorganization Grp., Inc. v. Nucor Corp.*, 466 F.3d 961 (11th Cir. 2006). There, the acquired assets already were in the market and plaintiffs lacked another way in. *See id.* at 966-68. Here, neither circumstance exists. Retrophin's ability to allege antitrust injury thus founders on *Gulf States*'s observation that, just as in *Lucas*, "the plaintiff's loss of an opportunity to acquire an asset is not a reason for finding [that acquisition] unlawful." *Id.* at 967 n.3 (quoting 2A Areeda, *supra*, ¶ 356, at 278).

Second, Retrophin lacks antitrust injury for the separate reason that any injury flows from an inability to take a course of conduct that, on its own theory, would not benefit consumers; therefore, Retrophin's injury is not "of the type the antitrust laws were intended to prevent." *Brunswick*, 429 U.S. at 489. This is because, if Retrophin is correct that Synacthen could enable

[5] Other courts recognize that *Glen Holly* conferred standing on the plaintiff "because it alleged it was a consumer." *Stanislaus Food Prods. Co. v. USS-POSCO Indus.*, No. CV F 09-05602010, WL 3521979, at *11 (E.D. Cal. Sept. 3, 2010). As *Stanislaus* reflects, competition by the *Glen Holly* plaintiff downstream did not provide any basis for standing.

meaningful entry (which the Complaint in no way supports), Retrophin's acquisition of Synacthen would reduce Retrophin's incentive to pursue its "very fast track" strategy of entering through RE-034 (MTD 10-11). Retrophin's Opposition is thus wrong that "Retrophin's ownership of Synacthen" could only produce a "positive competitive effect" (Op. 11). On the contrary, Retrophin complains of its inability to reap the benefits of reducing rivalry between RE-034 and Synacthen. *Cf. Original Appalachian Artworks, Inc. v. Granada Elecs., Inc.*, 816 F.2d 68, 74 (2d Cir. 1987) (affirming dismissal for lack of antitrust injury where plaintiff "would have benefited from any anticompetitive conduct"). Retrophin's gripe that it could not control both Synacthen and RE-034 shows that its interests fatally diverge from those of consumers and for that reason Retrophin lacks antitrust injury. *Ball Mem'l Hosp. Inc. v. Mutual Hosp. Ins. Inc.*, 784 F.2d 1325, 1334 (7th Cir. 1986) (Easterbrook, J.) (explaining the "problem in finding 'antitrust injury'" when "the plaintiffs and consumers have divergent rather than congruent interests"). "Poor champion[s] of consumers" such as Retrophin lack antitrust injury. *Id.* Tellingly, Retrophin fails to grapple with Questcor's cases demonstrating this elemental reason why Retrophin lacks antitrust injury.[6] Retrophin's only other response – that RE-034 "cannot be sold legally in the U.S." (Op. 11) – is no counter at all, because the same is true for Synacthen.

II. RETROPHIN FAILS TO ALLEGE COMPETITIVE HARM

Questcor identified three independent reasons why Retrophin fails to allege harm to competition: (i) any such harm, on Retrophin's allegations, is wholly speculative; (ii) Retrophin fails to identify any valid theory of competitive harm that satisfies the extremely narrow circumstances where courts permit claims based on the elimination of "potential" competition; and (iii) any harm is transient. Retrophin fails to meet all three.

1. *Competitive harm is speculative*. Retrophin's Opposition contends that it alleges competitive harm because "[f]oreclosure of entry" is "an injury to competition" (Op. 20). But as demonstrated, Retrophin's ability to enter through Synacthen is speculative as a matter of law; and Retrophin admits that it expects swiftly to enter through RE-034. Retrophin thus fails

[6] *E.g.*, *In re Baseball Bat Antitrust Litig.*, 75 F. Supp. 2d 1189, 1197-98 (D. Kan. 1999) (no antitrust injury where plaintiff deprived of course of conduct that would not benefit consumers).

sufficiently to plead foreclosure-based harm to competition. *See Allied Orthopedic Appliances Inc. v. Tyco Health Care Grp L.P.*, 592 F.3d 991, 996 n.1 (9th Cir. 2010) (foreclosure of competition must be "probable") (cited Op. 20); *Dickson v. Microsoft Corp.*, 309 F.3d 193, 208-09 (4th Cir. 2002) (affirming dismissal where complaint provided "no basis" for concluding that substantial foreclosure was "***likely***") (emphasis added); *Omega Envtl., Inc. v. Gilbarco, Inc.*, 127 F.3d 1157, 1163 (9th Cir. 1997) (no foreclosure when alternative paths to market exist); *Joyce Beverage of New York, Inc. v. Royal Crown Cola Co.*, 555 F. Supp. 271, 278 (S.D.N.Y. 1983) (no foreclosure where "numerous ways" and "viable alternative methods" to entry).

2. *No valid potential competition theory*. Retrophin also offers no answer to Questcor's showing (MTD 20) that Retrophin fails to allege a valid theory of competitive harm because Novartis never sought to enter through Synacthen. Retrophin concedes (Op. 20) that it is merely a "potential competitor." Retrophin could not argue otherwise. After all, neither Synacthen nor Retrophin currently competes with Acthar (Compl. ¶ 5). But Retrophin's allegations do not fall within the two narrow circumstances in which courts permit challenges to acquisitions that assertedly diminish potential competition.[7] The first, when the potential entrant exerts a constraint on the market,[8] plainly does not fit Retrophin's Complaint. Novartis never tried to enter (Compl. ¶¶ 4, 46) and Retrophin nowhere alleges that Novartis, when it held Synacthen, affected Questcor's behavior.

Retrophin's Complaint also fails to satisfy the second theory – the acquisition of a so-called "actual" potential entrant. Courts permit (albeit rarely) challenges to the acquisition of potential competitors under this theory only when (i) the acquired party comprised one of a tiny

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[7] *See BOC Int'l Ltd. v. FTC*, 557 F.2d 24, 27-28 (2d Cir. 1977) (no violation where "there is no showing that the acquiring firm would have entered the market but for the acquisition and if the acquiring firm is exerting no present influence on the market as a perceived potential entrant"); 1 ABA Section of Antitrust Law, Antitrust Law Developments 377 (7th ed. 2012) ("[M]ergers of potential competitors may be challenged on two theories: the 'perceived potential competition' theory and the 'actual potential competition' theory.").

[8] *See United States v. Marine Bancorp., Inc.*, 418 U.S. 602, 624-25 (1974) ("perceived potential competition" exists when a "firm's premerger presence on the fringe of the target market" affected behavior of firms in the market).

handful of potential entrants that (ii) was poised to enter absent the acquisition. *See, e.g.*, *Tenneco, Inc. v. FTC*, 689 F.2d 346, 352-53 (2d Cir. 1982) (rejecting potential competition challenge). But Retrophin does not allege that Novartis had any such ability or intention to enter into Acthar's markets in the United States through Synacthen. This makes Synacthen (as far as Acthar's indications go) no different from RE-034 or the numerous other "open source" synthetic ACTH compounds that, Retrophin admits, are seeking to enter (MTD 18, 22). For these reasons, Retrophin meets neither prerequisite to alleging an "actual" potential entrant: Retrophin affirmatively admits that Novartis was ***not*** poised to enter (Compl. ¶ 4); and it admits that numerous ***other*** potential entrants exist (MTD 15, 17-18).

This case thus presents precisely the circumstance where, as the very portion of the Areeda treatise Retrophin elsewhere cites explains, courts ought not permit challenges to the asserted elimination of potential competition: "Where the acquired firm is neither unique nor has already decided on entry, speculation may become excessive – as has indeed occurred in applying Clayton Act § 7 to mergers with 'potential competitors.'" 3 Areeda, *supra*, ¶ 701d, at 197-99 (cited Op. 2). This logic applies equally here, where the asset acquired never supported competitive entry by a well-resourced owner, despite (according to Retrophin) a significant entry incentive (Compl. ¶¶ 4, 36, 46).

Retrophin's counter – that the potential competition doctrine only filters out cases that "involve highly competitive markets" with "many competitors or potential competitors" (Op. 20-21) – is both legally and factually flawed. It is legally flawed because courts only recognize a diminution of competition when the acquired firm was poised to enter. *See BOC Int'l Ltd. v. FTC*, 557 F.2d 24, 29 (2d Cir. 1977) (rejecting potential competition theory as "uncabined speculation" when no "reasonable probability of entry in the near future").[9] It is factually flawed because, Retrophin admits, (i) Synacthen never was poised to enter the United States when in Novartis' hands; and (ii) other "open source" entry paths (such as RE-034) exist and, therefore, Novartis was not merely "one of a handful of potential entrants" (Compl. ¶ 4; MTD 15, 17-18).

[9] *See also, e.g.*, *Marine Bancorp*, 418 U.S. at 639 (inquiry is whether acquiring firm was potential entrant); *FTC v. Atl. Richfield Co.*, 549 F.2d 289, 300 (4th Cir. 1977) (no antitrust violation where acquiring firm was not committed potential entrant).

Retrophin is really asking this Court to forge new law and hold that, whenever a prospective entrant fails to obtain an asset that, it says, would help entry – even when the asset did not help entry before and even when other ways to enter exist – competition is harmed. Retrophin's Opposition tellingly cites ***no case*** for this proposition. And there is none. In any event, for two reasons, Retrophin's Complaint presents a poor vehicle for minting such a doctrine. First, the Complaint does not allege that Retrophin's ability to compete with Acthar through Synacthen is greater than Novartis'. Because Retrophin admits that giant Novartis declined to try to compete in the United States with Acthar through Synacthen (Compl. ¶ 4), there is no basis to conclude – and conclusive reasons to doubt – that Synacthen in Retrophin's hands would have improved competition relative to when Novartis owned Synacthen. Second, Retrophin's admission that RE-034 gives it another entry path (Compl. ¶ 57) shows that depriving potential entrants of Synacthen fails to identify any competitive harm.

3. ***Any harm is transient.*** Finally, Retrophin fails to meet Questcor's argument that any harm is transient and, therefore, insufficient to comprise competitive harm. Retrophin has told investors it expects swift entry through RE-034, with Phase III clinical trials expected ***this year*** (MTD 18-19). But Retrophin never alleges when it expected ***Synacthen*** to enter Phase III trials. Whether or not Questcor has enjoyed a monopoly, Retrophin admits it does not expect it to persist for "an indefinite period" (Op. 21-22) in light of RE-034's speedy development. Retrophin's contention that the facts in Questcor's cases differ from those here (MTD 20-21) cannot mask the general principle for which they stand: a "temporary harmful effect" on competition is not actionable. *E.g.*, *Am. Prof'l Testing Serv., Inc. v. Harcourt Brace Jovanovich Legal & Prof'l Publ'ns, Inc.*, 108 F.3d 1147, 1151 (9th Cir. 1997); *Adaptive Power Solutions, LLC v. Hughes Missile Sys. Co.*, 141 F.3d 947, 952 (9th Cir. 1998) (same). That principle bars Retrophin's Complaint.

III. RETROPHIN FAILS TO ALLEGE MARKET OR MONOPOLY POWER

Retrophin contends that its Complaint sufficiently alleges (i) direct; and (ii) indirect evidence of monopoly power. Retrophin is wrong.

1. *No sufficient direct evidence*. "[D]irect evidence" of market power is rare.[10] And with good reason: an allegation (such as Retrophin's, Op. 17) that a firm prices above a competitive level begs the question of what the competitive level is.[11] Retrophin's allegations fail to "directly" allege market power here. The sole allegation to which Retrophin points is that Questcor raised Acthar's price per vial from $50 to $28,000 (Op. 3-4). But raising prices indicates monopoly power only when higher prices cause output to fall.[12] Here, Retrophin does not allege that Questcor restricts output. In fact, precisely the opposite is true. Questcor invested in Acthar, making the drug useful to many more patients (Compl ¶ 3).[13] Retrophin concedes significant demand for Acthar (Compl. ¶¶ 3, 40, 43). Under Retrophin's allegations, in other words, it is far more plausible that the quality-adjusted price of Acthar ***declined*** rather than rose.[14] Thus, no facts "nudge" Retrophin's "direct evidence" argument over the line from "conceivable" to "plausible." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 547 (2007).

2. *No sufficient circumstantial evidence*. Retrophin's Opposition also fails to meet Questcor's showing that Retrophin fails to sufficiently allege circumstantial evidence of market power because Retrophin does not allege high entry barriers (MTD 17-19). The primary

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[10] *E.g.*, *MetroNet Servs. Corp. v. U.S. W. Commc'ns*, 329 F.3d 986, 1003 (9th Cir. 2003) ("Because direct evidence of [monopoly] power . . . is rarely available, courts generally rely on circumstantial evidence of market power."); *United States v. Microsoft Corp.*, 253 F.3d 34, 51 (D.C. Cir. 2001) (en banc) (per curiam) ("direct proof" is "only rarely available"); *Ford v. Cascade Health Servs.*, No. 03-6256-TC, 2006 WL 1805954, at *7 (D. Or. June 29, 2006) (same).

[11] *See, e.g.*, *In re Ebay Seller Antitrust Litig.*, No. C 07-01882 JF (RS), 2010 WL 760433, at *5 (N.D. Cal. Mar. 4, 2010) ("Evidence that eBay has raised prices over a period of years . . . proves nothing with respect to whether the prices are supracompetitive.").

[12] *See, e.g.*, *Forsyth v. Humana, Inc.*, 114 F.3d 1467, 1476 (9th Cir. 1997) ("With no accompanying showing of restricted output, however, the plaintiffs have failed to present direct evidence of market power."); *Wallace v. Int'l Bus. Machs. Corp.*, 467 F.3d 1104, 1107 (7th Cir. 2006) (Easterbrook, J.) ("reduction of output" is "essential to monopoly"); *Saturday Evening Post Co. v. Rumbleseat Press, Inc.*, 816 F.2d 1191, 1199 (7th Cir. 1987) (Posner, J.) (same).

[13] *See* MTD 3; Popofsky Decl. Ex. E, at 70 (illustrating increasing demand for Acthar).

[14] *See, e.g.*, *Roland Mach. Co. v. Dresser Indus., Inc.*, 749 F.2d 380, 395 (7th Cir. 1984) (Posner, J.) (conduct procompetitive when it leads to lower "quality-adjusted price to the consumer."); *Kochert v. Greater Lafayette Health Servs., Inc.*, 463 F.3d 710, 719 (7th Cir. 2006) (similar); *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, 1303, 1306 (W.D. Mich. 1996) (similar).

purported entry barrier Retrophin identifies is "the difficulty of developing a new product" (Op. 18). But Retrophin admits it developed RE-034 quickly from scratch (Compl. ¶ 57) and repeatedly reassures shareholders that RE-034 will swiftly obtain FDA approval (Popofsky Decl. Ex. B, at 24). Retrophin also tells its shareholders that synthetic ACTH compounds are "open source," that "anyone" can develop one, and that numerous firms are doing just that (*Id.* at 22-24). These admissions fatally contradict, and thus entitle this Court to disregard, conclusory allegations (Compl. ¶ 58) that developing an Acthar competitor is difficult or expensive.[15]

Retrophin, therefore, retreats to the argument that the need to obtain FDA approval is a sufficient entry barrier (Op. 18-19). But Retrophin cannot have it both ways. If FDA approval is a sky-high entry barrier, conferring on Questcor an "air tight monopoly" (Op. 19), then Retrophin's claim of injury from inability to obtain Synacthen is wholly speculative. *See supra* pp. 4-8. Put differently, if the Court accepts Retrophin's entry barrier argument, it must dismiss the Complaint for failure to allege antitrust standing or competitive injury. Retrophin's Opposition offers only silence in the face of this fatal contradiction.[16]

Retrophin also offers no answer to Questcor's showing that FDA approval is not a legally cognizable entry barrier here, because entry barriers only include "additional long-run costs" that were "***not*** incurred by incumbent firms but must be incurred by new entrants." *Rebel Oil Co. v. Atl. Richfield Co.*, 51 F.3d 1421, 1439 (9th Cir. 1995) (internal quotations omitted) (emphasis added). Retrophin lacks any factual response, because it identifies no additional regulatory hurdle that Synacthen confronts that Questcor did not face when it entered with Acthar.[17] Retrophin's legal response – that a "legal license requirement" always constitutes an entry

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[15] *See, e.g.*, *Hirsch v. Arthur Andersen & Co.*, 72 F.3d 1085, 1095 (2d Cir. 1995) (sustaining dismissal where "attenuated allegations" "are contradicted both by more specific allegations in the Complaint and by facts of which [the court] may take judicial notice"); *In re Livent, Inc. Noteholders Secs. Litig.*, 151 F. Supp. 2d 371, 405-406 (S.D.N.Y. 2001) (same).

[16] Retrophin's attempt to paint Questcor's arguments as contradictory (Op. 19) ignores that Questcor's arguments take each of Retrophin's contradictory allegations in turn.

[17] Retrophin alleges that Acthar's "orphan drug designation" for IS comprises an entry barrier (Op. 18). However, Retrophin's investor statements make plain that this supposed barrier (unexplained by Retrophin) does not block RE-034 (MTD 5-7).

barrier (Op. 18) – proves too much. *Rebel Oil* plainly established no such a rule.[18] Retrophin's cases do not hold otherwise.[19]

IV. RETROPHIN'S STATE LAW CLAIMS FALL WITH ITS DEFICIENT FEDERAL CLAIMS

Retrophin admits that its state law claims are entirely derivative of its federal claims (Op. 24-25). Those claims thus fail for the same reason as Retrophin's deficient federal claims.[20]

V. THE COURT SHOULD DENY LEAVE TO AMEND

This Court should deny Retrophin's request for leave to amend (Op. 25). First, Retrophin elected to stand on its Complaint instead of amending as of right upon receiving Questcor's Motion. When, as here, a plaintiff clings to the original version of its pleading, dismissal is proper. *Lipton v. Pathogensis Corp.*, 284 F.3d 1027, 1038 (9th Cir. 2002) (dismissal with prejudice appropriate where "[p]laintiff had ample opportunity to amend" but stood on its pleadings). Second, granting leave to amend would be futile.[21] For one thing, as demonstrated, Retrophin cannot allege likely FDA approval of Synacthen for Acthar's indications in good faith, particularly when Novartis never attempted entry despite "decades worth of safety and efficacy data" (Op. 14). For another, Retrophin cannot allege that Synacthen offered a uniquely important entry vehicle, or that Retrophin is uniquely situated to enter, in light of (i) RE-034's

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[18] *See also Barr Labs., Inc. v. Abbott Labs.*, 978 F.2d 98, 113 (3d Cir. 1992) (rejecting notion that "any form of government approval . . . required for market entry automatically establishes a barrier to entry"). To the extent entry barriers also include "factors" that "deter entry," *Rebel Oil*, 51 F.3d at 1439, RE-034 shows no such deterrence here.

[19] *Masimo Corp. v. Tyco Health Care Grp., L.P.*, No. CV 02-4770 MRP, 2004 WL 5907538, at *4 (C.D. Cal. June 10, 2004), did not, contrary to Retrophin's representation (Op. 18), opine on whether FDA approval constitutes an entry barrier. As for *Se. Mo. Hosp. v. C.R. Bard, Inc.*, 642 F.3d 608, 623 (8th Cir. 2011), Retrophin cites the dissent (Op. 19).

[20] Retrophin incorrectly describes (Op. 24-25) the statute that superseded *Cal. ex rel. Van de Kamp v. Texaco, Inc.*, 46 Cal. 3d 1147, 1168-68 (1988). As stated in *Stop Youth Addiction, Inc. v. Lucky Stores, Inc.*, 17 Cal. 4th 553, 570 (1998), that amendment did *not* impact *Texaco's* Cartwright Act holding.

[21] *See also In re Dynamic Random Access Memory (DRAM) Antitrust Litig.*, 546 F.3d 981, 990 (9th Cir. 2008) ("A court properly exercises its discretion in denying leave to amend if the proposed amendment would be futile."); *Nunes v. Ashcroft*, 375 F.3d 805, 808 (9th Cir. 2004) ("Futility alone can justify the denial of a motion for leave to amend.").

development and assertedly swift entry path; and (ii) admissions that ACTH is "open source." These realities, as demonstrated, doom Retrophin's case.

CONCLUSION

For the foregoing reasons, Questcor's Motion to Dismiss Retrophin's Complaint with Prejudice should be GRANTED.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that, on April 25, 2014, I caused true and correct copies of the attached Reply Memorandum in Support of Motion to Dismiss Plaintiff's Complaint with Prejudice to be served by electronic mail upon:

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